ascertain ability to use a computerized program for guideline review).

Written requests, together with the signed confidentiality statement, should be mailed to: Cheryl Campbell, Panel Manager; Technical Resources International, Inc. (TRI), 3202 Tower Oaks Boulevard, Rockville, Maryland 20852-4200. (Fax number: (301) 231-6377.) If faxing the request, the original signed confidentiality statement must also be mailed.

Automated review process: A computerized guideline review process, supported by AHCPR, enables comments to be entered on a specially formatted diskette. A diskette will be furnished, with instructions, to those requesting the draft guideline. To facilitate the review process, it is recommended that reviewers use the computer diskette to record their comments. Reviewers who do not use a diskette will be asked to provide typewritten comments.

Requests for a copy of the draft guideline should include the following information regarding the computer system to be used for reviewing the guideline: Type of computer: IBM/compatible or Macintosh; and if IBM/compatible: the size of disk drive (3.5" or 5.25").

For technical assistance or questions regarding computer resources, call the Guideline Review Technical Support at (301) 231-5250 ext. 100 and ask for Ms. Cheryl Campbell.

FOR ADDITIONAL INFORMATION: Additional information on the guideline development process is contained in the AHCPR Program Note, "Clinical Practice Guideline Development," (AHCPR Publication No. 93-0023) dated August 1993.

This document may be obtained from the AHCPR Publications Clearinghouse, P.O. Box 8547, Silver Spring, MD 20907; or call toll-free: 1-800-358-9295.

Dated: December 1, 1995.

Clifton R. Gaus,

Administrator.

[FR Doc. 95-29865 Filed 12-6-95; 8:45 am]

BILLING CODE 4160-90-M

Food and Drug Administration

[Docket No. 95E-0300]

Determination of Regulatory Review Period for Purposes of Patent Extension; CELLCEPT®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for CELLCEPT® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product CELLCEPT® (mycophenolate mofetil). CELLCEPT® is indicated for the prophylaxis of organ rejection in patients receiving allogeneic renal transplants. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for CELLCEPT® (U.S. Patent No. 4,753,935) from Syntex, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated October 2, 1995, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of CELLCEPT® represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for CELLCEPT® is 2,479 days. Of this time, 2,304 days occurred during the testing phase of the regulatory review period, while 175 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective*: July 21, 1988. The applicant claims June 24, 1988, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 21, 1988, which was 30 days after FDA receipt of IND 31,747 on June 21, 1988.

2. *The date the application was initially submitted with respect to the human drug product under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357)*: November 10, 1994. FDA has verified the applicant's claim that the new drug application (NDA) for CELLCEPT® (NDA 50-722) was initially submitted on November 10, 1994.

3. *The date the application was approved*: May 3, 1995. FDA has verified the applicant's claim that NDA 50-722 was approved on May 3, 1995.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 824 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before February 5, 1996, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before June 5, 1996, for a determination regarding whether the

applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 30, 1995.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 95–29768 Filed 12–6–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95E–0299]

Determination of Regulatory Review Period for Purposes of Patent Extension; ZINECARD™

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ZINECARD™ and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product ZINECARD™ (dexrazoxane). ZINECARD™ is indicated for reducing the incidence and severity of cardomyopathy associated with doxorubicin administration in women with metastatic breast cancer who have received a cumulative doxorubicin dose of 300 milligrams per square meter and who, in their physician's opinion, would benefit from continuing therapy with doxorubicin. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ZINECARD™ (U.S. Patent No. 4,275,063) from British Technology Group Ltd., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated October 5, 1995, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ZINECARD™ represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for ZINECARD™ is 2,748 days. Of this time, 1,546 days occurred during the testing phase of the regulatory review period, while 1,202 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective*: November 18, 1987. The applicant claims September 25, 1987, as the date the investigational new drug application (IND) for ZINECARD™ (IND 30,617) became effective. However, FDA records indicate that the agency received IND 30,617 on September 22, 1987. IND 30,617 was placed on clinical hold on October 22, 1987, and was removed from hold on November 18, 1987. The date IND 30,617 was removed from hold, November 18, 1987, is the IND effective date.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act*: February 10, 1992. The applicant claims February 7, 1992, as the date the new drug application (NDA) for ZINECARD™ (NDA 20–212) was initially submitted. However, FDA records indicate that FDA received NDA 20–212 on February 10, 1992, making February 10, 1992, the beginning of the NDA regulatory review period.

3. *The date the application was approved*: May 26, 1995. FDA has verified the applicant's claim that NDA 20–212 was approved on May 26, 1995.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,825 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before February 5, 1996, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before June 5, 1996, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit